Chapter 880 and 881

- **Stakeholder Process and Recommendations (October 5, 2008)**
  Toxic Chemicals in Children's Products

Report of Stakeholder Process and Recommendations to Commissioner, Maine Department of Environmental Protection

Toxic Chemicals in Children's Products Stakeholder Meetings

Public Laws 2007 Ch 643

Summary

The 123rd Legislature passed An Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products Public Law 643 (H.P. 1432-LD 2048). The law called for the Commissioner of Environmental Protection to convene a Stakeholder group and seek recommendations from the stakeholders on three components of the new law:

- The development of a protocol to be utilized for the designation of priority chemicals;
- The responsibilities, activities and proposed rules necessary to implement Title 38, Chapter 16-D; and
- Stakeholder Issues of Concern.

This report summarizes the stakeholder convening process and the discussions undertaken in the stakeholder meetings. The report focuses on the larger issues and issues which absorbed significant discussion time. The discussions are grouped under the three broad categories in which the Commissioner sought recommendations. In addition all written comments submitted are attached as Appendix A.

The full stakeholder group did not achieve any consensus recommendations (i.e. by vote) during this process. There was however considerable rich discussion and many valuable thoughts offered for the Commissioner's consideration. Some highlights of general agreement include:

- There was agreement that chemicals to which children are exposed and which have a known harmful impact are a priority.
- The need for targeted requests for data on priority chemicals was supported by all stakeholders.
- All stakeholders agreed existing publicly available information should be collected and used by DEP.
- Stakeholders agreed to share existing lists of chemicals that might offer the Maine Department of Environmental Protection (DEP) and Center for Disease Control (CDC) additional guidance on prioritizing chemicals for designation.
- The stakeholders agreed there should be an opportunity for manufacturers and distributors to request DEP go directly to industry funded independent contractors for alternatives assessment. The Department should consider identifying three to four assessors/contractors including some suggested by Industry that can be available to complete alternatives assessments.
- It was agreed that when genuine confidential business information is identified there should be a clear process that is available that legitimately protects companies but is not available as an all purpose shield contrary to the intent of the legislation.
- The stakeholder group agreed that there were efficiencies in "batching" priority chemicals into single rule makings.

While the stakeholder process did not produce significant recommendations or many points of agreement among stakeholders, it did help move the parties closer to a trusting productive interaction.

Several stakeholders, including industry, health and environmental advocate representatives have agreed to independently organize themselves to continue dialogue and look for additional opportunities to come closer together in supporting DEP's implementation of this statute.

Stakeholder Convening Process

The Department of Environmental Protection contracted for professional services with Naomi Mermin Consulting to design a stakeholder process in response to the legislative language included in Public Law 643. The stakeholder process was begun in February 2009 with a projected conclusion in June 2009. An initial series of three stakeholder meetings were developed following the three key components of the law specifically identified for stakeholder input (i.e. Development of a protocol for designation of priority chemicals; responsibilities, activities and proposed rules necessary to implement Title 38, Chapter 16-D; and Stakeholder Issues of Concern). Through the stakeholder convening process a fourth meeting was added. The Department has maintained a list of "interested parties" from the legislative process and added additional stakeholders as they have indicated interest. Independent experts from two Universities and the United States Environmental Protection Agency were explicitly invited to participate. This resulted in broad stakeholder participation as intended by the statute (i.e. "shall convene a stakeholder group that includes representatives of consumer product manufacturers, chemical manufacturers, retailers, trade associations, nonprofit health organizations, business and environmental groups and other affected parties and shall invite the participation of independent experts with relevant experience with chemicals. "). The meetings were held on March 6, 2009, March 27, 2009, April 27, 2009 and May 4, 2009. Complete agendas and meeting highlights including attendees are contained in Appendix B.

Stakeholder Input on Development of a protocol to be utilized for the designation of priority chemicals.

The Department presented preliminary draft implementing rules as a "straw man" proposal to the stakeholder group. The preliminary draft rule offered full rule making as the "protocol" or process for designation of priority chemicals. (Appendix C).

There was an objection raised by industry to the provision of a preliminary draft rule for discussion; however there was no objection from any stakeholders to the use of formal rulemaking as the protocol for designation of a priority chemical. During the final stakeholder meeting one stakeholder mentioned that despite early criticism of DEP providing a preliminary draft rule, it had proved valuable to the process.

The stakeholders asked and received clarification that each rulemaking could accommodate designation of multiple chemicals. Batching of chemicals in rulemaking was supported as an efficient scheme.

There was significant discussion regarding what factors could be prioritized or weighted more heavily during rulemaking. There was agreement that chemicals to which children are exposed and which have a known harmful impact are a priority. There was no consensus however on a general rule to determine exposure or a firm definition of "harmful impact". The health and environmental advocates achieved a consensus that "chemicals present in umbilical blood, breast milk, and maternal blood" should be prioritized. Several industry representatives either were opposed to this prioritization or felt detection of a chemical could not be the sole determinant of prioritization efforts.

Several industry group comments identified other issues such as threshold levels for "presence" and "exposure", and concern that reporting requirements were broad and seemingly open ended, but no consistent scheme was offered to alleviate these concerns. The legislators present clarified repeatedly that these issues had been raised during the legislative discussion and it was intentional that the law provided considerable latitude to DEP to designate chemicals without creating an excessively burdensome process of information collection or analysis by DEP. It was clarified in the stakeholder process that DEP was looking at chemicals which are intentionally included in a product.

The need for targeted requests for data was supported by all stakeholders. Industry comments focused on tailoring data request to ensure unneeded or duplicative information was not requested. Several stakeholders advocated that safe guards be in place to ensure that all relevant data and studies be provided for consideration not just those chosen/offered by industry. All stakeholders agreed existing authoritative and credible publicly available information should be collected and used by DEP.

There was considerable discussion of how chemicals of high concern could be selected to go through rule making for designation as priority chemicals. It was clarified that the department could only accept informal guidance on how to move from chemicals of high concern to priority chemicals because the legislation is clear on the roles of DEP and CDC in making these decisions.

Stakeholders agreed to share existing lists of chemicals that might offer DEP/CDC additional guidance on prioritizing chemicals for designation. Matt Prindiville of the Natural Resources Council of Maine was the only stakeholder to provide a list (Appendix D) drawn from chemicals which overlapped on the REACH SIN list, the Stockholm Treaty, and Norway List of substances of High Concern. Stakeholders felt the exercise was valuable but needed further development that could not occur within the time constraints of the stakeholder process. Industry representatives and health and environmental advocates, led by Andy Hackman (representing the Consumer Specialty Products Association) and Matt Prindiville (representing the Alliance for a Clean and Healthy Maine) are organizing continued discussion of prioritization and review of lists. DEP staff indicated that any agreement on prioritization from such a broad section of stakeholders would certainly be of interest to DEP as it moves forward with designation.

Stakeholder Input on responsibilities, activities and proposed rules necessary to implement Title 38, Chapter 16-D.

There were four distinct areas covered under this section of the stakeholder process: Review of the fees the department has the authority to assess on manufacturers and distributors upon submission of

notification on designated priority chemicals; Review of the fees the department has the authority to assess if a requested acceptable alternatives assessment is not timely provided; Components of an "acceptable" alternatives analysis; and the process for banning products.

Fees for Priority Chemicals Designation.

DEP provided a preliminary draft rule/straw man for Fees (Appendix C). DEP proposed a fee of $500 to accompany disclosure reporting on priority chemicals as a starting point for discussions. The proposed fee amount was derived from DEP's experience managing information under Maine's mercury products laws. Annual pesticide registration fees were suggested by industry as a better comparison and would be at a lower level of $125. Other stakeholders suggested looking at pharmaceutical registration fees which were over $1000. There was no consensus on where the fee should be but a general agreement that the fees were meant to accurately cover the costs of data collection and management. Health and Environmental representatives are concerned that a fee of $500 will not sufficiently cover DEP's costs to provide robust data gathering, management and review and industry argued that in many cases sufficient information already existed in the public sphere and the fee represented an undue burden. Andy Hackman, representing the Consumer Specialty Products Association, offered and subsequently provided to the department a chart on pesticide fees charged by states (Appendix E)

The possibility of exploring a graduated fee system and setting boundaries on data requested were explored but no consensus emerged. It may be appropriate to revisit the fee structure after there is some implementation experience.

Review of the Fees for Alternatives Assessment

The proposed fee is applied at the Departments discretion, applied when a manufacturer or distributor fails to provide, in a timely manner, an alternatives assessment acceptable to the department. The fee is to cover the costs incurred for DEP to hire a contractor to prepare an independent alternative assessment.

The stakeholders, both industry and health and environmental representatives, agreed there should be an opportunity for manufacturers and distributors to request DEP to go directly to an industry funded independent contractor. Both Industry and health and environmental representatives agreed the Department should consider identifying three to four assessors/contractors including some suggested by Industry that can be available to complete alternatives assessments.

Industry expressed concerns about the open ended nature of the discretionary fee and asked that cost parameters and data parameters be developed. Independent expert Pam Eliason offered her experience that the Toxics Use Reduction Institute was able to complete 15 different assessments in 10 months for a total cost of $250,000.

Components of an Acceptable Alternative Assessment

The DEP in the preliminary draft rule/straw man Chapter 880 regulation (Appendix C) offered an outline of the components of an acceptable alternatives assessment.

There were several concerns raised about the ability of manufacturers and distributors to acquire some of the information required (i.e. information on functionally equivalent products made without the priority chemical and information on alternatives). It was suggested while some information would be requested from industry perhaps there could be greater clarity about who provides what information.

Health and environmental advocates suggested adding rules inviting public comments on the Alternatives Assessment. They further suggested that the rule require documentation of industry's investigation of alternatives including what studies were used to find/not find alternatives. A procedure for businesses to document their attempts to get data from suppliers and to identify alternatives should be considered. Such a system would offer a verification of industries attempts to comply.

There was some concern raised about the preliminary draft rules use of "for sale in the US" as criteria for whether an alternative was available, with the suggestion that DEP not limit the universe of alternatives to the US.

All the industry representatives expressed concern about specifying the Green Screen methodology within the regulation.

There was considerable discussion of "costs" and which costs could be considered. While several stakeholders and experts identified that cost was inherently part of "advantages and disadvantages" of an alternative, industry felt insufficient consideration was being given to the cost and safety concerns raised by alternatives. Health and environmental representatives stressed the long term costs of toxic chemicals and provided the recent study "An Economic Cost Assessment of Environmentally related Childhood Diseases in Maine." authored by Mary E. Davis and attached as Appendix F

Process for banning products.

The statute provides the authority to ban products containing a priority chemical if the board finds the distribution of the product directly or indirectly exposes children and vulnerable populations to the priority chemical and one, or more, safer alternatives are available at a comparable cost. The preliminary draft rule follows the statute very closely. Some changes in language however were of concern to advocates. The addition of "wide" to the presumption that an alternative is available if the alternative is in *wide* use in the United States, was seen as expanding the threshold beyond the language of the statute. Similar concern about the phrase "consider all relevant evidence" was raised as it is hard to define and could offer an opportunity for argument. It was suggested the language be narrowed.

Stakeholder Issues of Concerns

Three stakeholder issues of concern were identified and agreed on for discussion by the stakeholder group. Several additional stakeholder issues of concern were raised in individual stakeholder comments provided in written comments (see Appendix A). The three issues were economic concerns (of both action and inaction), confidential business information, and DEP resources and ability to designate more than the minimum number of chemicals required by statute.

Economic Impacts

The discussion of economic impacts centered on a split between industry groups and health and environmental advocates. The industry groups argued that each level of action, from the creation of a list of chemicals of high priority through potential banning of use of chemicals in a specific product had excessive negative impacts on industry which would have broad negative economic impacts including loss of jobs, restricting American manufacturers competitiveness and ultimately higher costs to consumers or removal of valuable products from the market place. The health and environmental advocacy groups argued that the law successfully uses the market to shift to safer chemicals which will result both in short term winners and losers within industry but more importantly long term economic savings through reduction of negative impacts such as learning disabilities, cancers and environmental degradation. While there was a rich discussion there was no consensus or recommendation made on how the commissioner might balance or alleviate negative economic impacts.

Confidential Business Information

The statute and the preliminary draft rules/straw man proposals looked at in the stakeholder process had no explicit process for identification of and protection of confidential business information. Industry was vocal in calling for such protection and advocates were wary of such a process being a method of undermining the core public disclosure/consumer information goals of the statute. No consensus emerged on a specific scheme of protection for confidential business information, it was agreed that when genuine confidential business information is identified there should be a clear process that is available that legitimately protects companies but is not available as an all purpose shield contrary to the intent of the legislation. Industry offered that such a process clearly articulated could be more efficient for all parties then having a court determine which information is legitimately confidential and which is not.

DEP resources and ability to designate m ore than the minimum number of chemicals required by statute.

The stakeholder group had already agreed that there were efficiencies in "batching" priority chemicals into single rule makings. DEP reiterated its ability to meet the minimum of 2 priority chemicals designated by 2011 but did explain that were some increases in costs/staff time as additional priority chemicals were added to a rule making. Advocates asked if there were opportunities for pursuing grant support. Industry stakeholders expressed concerns about putting too many chemicals through in a batch creating a bottleneck which would leave the chemicals stigmatized without opportunity to make it fully through the process. Some advocates felt this was not a legitimate concern as listing as a priority chemical had a minimal impact of requiring industry to provide information. Ultimately, the stakeholders agreed that working together they might be able to support a priority "batch" or list. Preliminary ideas for how to work together were discussed. A commitment was made by industry and the environmental and health advocates for them to explore continued dialogue beyond the stakeholder process.

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